

Appl. No. : 09/575,429  
Filed : May 22, 2000

being configured to reduce the splashing of said fluid specimen during collection, testing, transport and storage.

22. (Added) A specimen cup as in Claim 1, wherein said lid is threaded to mesh with threads on a rim of said container, the meshing of said lid threads with the rim threads providing a substantially sealed closure.

23. (Added) A specimen cup as in Claim 1, wherein said lid is independent of said container.

### **REMARKS**

#### **Rejections Under 35 U.S.C. §112**

The Examiner has rejected Claim 1-16 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, the Examiner has found that the language of Claims 1-16 reciting a cassette “custom integrated” with the container renders the aforementioned claims vague and indefinite as to the intended structural relationship. In response, Applicant has amended Claim 1 to recite “a cassette *slidably received within a receptacle integrated* with said container, *wherein said receptacle extends vertically below said lid.*” (*Emphasis added*). Applicant submits that the rejections for indefiniteness are overcome.

The Examiner has also found that the language of Claims 3 is vague and indefinite as to what structure is intended by “flat face design.” Applicant has amended Claim 3 to recite “a *recessed flat face configured* to move a viewing area closer to said cassette” (*emphasis added*). Applicant submits that the rejections for indefiniteness are overcome.

The Examiner has also found that the language of Claims 9 is vague and indefinite as to the placement of the “flap” to achieve the cited function of preventing splashing. In response, Applicant has amended Claim 9 to recite “a *hinged flap adjacent to a rim of said container, the hinged portion of the flap being affixed to an interior surface of said container in a position which partially blocks the opening of said container, said flap being configured to reduce the splashing of ... said fluid specimen...*” (*emphasis added*). Applicant submits that the rejections for indefiniteness are overcome.

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### **Allowable Subject Matter**

The Examiner has further stated that Claims 2-3 and 16 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant thanks the Examiner for extending this courtesy and has rewritten Claim 2-3 and 16 as Claims 17-19, respectively. In light of the amendments herewith, Applicant has chosen to retain Claims 2-3 and 16, as amended, for claim differentiation purposes.

The Examiner has further stated that Claims 3 and 9-10 would be allowable if written to overcome the above-mentioned rejections under 35 U.S.C. §112, second paragraph. Applicant thanks the Examiner for extending this courtesy and, as outlined above, Applicant has amended Claims 3 and 9-10 in response to the Examiner's rejections of the claims under §112, second paragraph. Accordingly, Applicant has rewritten amended Claims 3 and 9-10 in independent form including all of the limitations of the base claim and any intervening claims, as Claims 20 and 21, respectively. As previously stated, Claim 3 has been rewritten as independent Claim 18. In light of the amendments herewith, Applicant has chosen to retain Claims 3 and 9-10, as amended, for claim differentiation purposes.

### **Rejections Under 35 U.S.C. §102 and 35 U.S.C. §103**

The Examiner has rejected Claims 1 and 4-8 as being clearly anticipated under 35 U.S.C. § 102(b) by PCT application WO 97/33519 (Cipkowski) (WO '97 hereafter) or by U.S. Patent No. 5,916,815 (Lappe). The Examiner has also rejected Claims 11-15 as being unpatentable under 35 U.S.C. § 103(a) over WO'97 and Lappe. Specifically, the Examiner maintains that "when the cover is attached to the container, the lid and all its attachments, are integrated with the container." Office Action at p. 3.

Applicant does not dispute the Examiner's finding, but nevertheless submits that Claim 1, as amended, distinguishes the art of record. Claim 1, upon which Claims 2-16 depend, recites a "container having a top opening [...]*a cassette slidably received within a receptacle integrated with said container...and a lid configured to cover said top opening with the cassette inside, wherein said receptacle extends vertically below said lid.*" (*Emphasis added*).

The asserted prior art, in contrast, does not teach or suggest anything about a cassette which is slidably received within a receptacle integrated the container wherein the receptacle

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*extends vertically beneath the lid*. Rather, the references either teach the *attachment* of a card *to the lid* of the container or sliding the card through a *horizontal slot* in the lid in order to perpendicularly suspend the card from the lid into the container below. Lappe teaches a drug assay system comprising a collection cup 10, a lid 18, and a test card 22 affixed perpendicular to the collection cup lid 18 and extending downward into the collection cup 10. *See*, Col. 3, l. 66-Col. 4, l. 5. Lappe does not teach or suggest a receptacle which extends vertically below the lid, as recited in amended Claim 1, whether or not the lid is considered integrated with the container. WO '97 teaches a drug abuse kit comprising a container 11 having a closure cap 22 with a slit 19 configured to receive a drug test card 25. *See*, Col. 3, ll. 27-47. Although the slit 19 of WO '97 is below the closure cap 22, only a horizontal opening or slot, which does not extend vertically beneath the lid (as recited by amended Claim 1), is apparent.

Claim 4 has also been amended to reflect the changes to Claim 1. An example of the aforementioned receptacle is described in the specification and in Claim 4, through the configuration of a container having custom channels into which the cassette is slid in order to properly orient the cassette within the container. *See*, '429 Application, p. 6, ll. 19-29.

Accordingly, Applicant traverses the Examiner's §102 rejections of base Claim 1 and 4-8 have been overcome. Furthermore, since neither of asserted references, alone or in combination, teaches or suggests a specimen cup having the unique features recited in newly amended Claim 1, in addition to the materials recited in Claims 11-15, Applicant traverses the Examiner's §103 rejections Claims 11-15.

Accordingly, Applicant submits that as the art of record does not teach or suggest an invention having each of the recited features in the claims as amended, and, as a result, the amended claims are allowable over the art of record.

#### **Additional Amendments and Added Claims**

Claims 1-16 have also been amended to correct typographical and other inadvertent errors, and to better protect the subject matter Applicant regards as the invention, in addition to the aforementioned reasons. These amendments to correct inadvertent errors are also reflected in the newly added Claims 17-21. In addition, Claims 11-15 have been amended to recite the

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intended dependency from Claim 11, rather than Claim 10. These typographical amendments do not add any new matter and are fully supported by the specification.

Claims 22 and 23 have also been added to better claim the subject matter Applicant regards as the invention. These amendments add no new matter and are fully supported by the specification. For example, Claim 22 recites, *inter alia*, "said lid is threaded to mesh with threads on a rim of said container, the meshing of said lid threads with the rim threads providing a substantially sealed closure," support for which can be found on page 5, lines 9-11. Claim 23 which recites, *inter alia*, "said lid is independent of said container," is supported by the specification as filed at page 5, lines 9-11, in addition to at page 7, lines 20-22. *See also*, Fig. 1. Accordingly, Applicant submit that these added claims are in condition for allowance and request the same.

### CONCLUSIONS

In view of the foregoing amendments and remarks, Applicant respectfully submits that the application as amended is in condition for allowance and respectfully requests the same. If, however, some issue remains that the Examiner feels can be addressed by Examiner's Amendment, the Examiner is cordially invited to call the undersigned for authorization.

Attached hereto is a separate paper entitled VERSION OF THE AMENDMENTS SHOWING CHANGES MADE, in which additions are shown in double underlining and deletions are shown ~~stricken through~~.

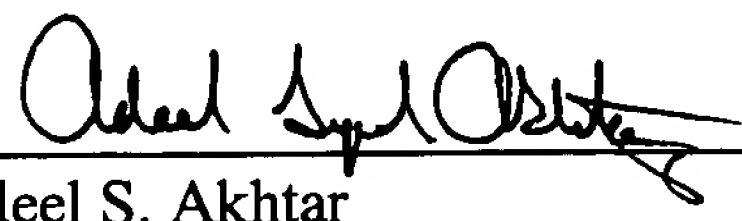
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: October 7, 2002

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## VERSION SHOWING CHANGES MADE TO THE CLAIMS

Claims 17-23 have been added.

Claims 1-16 have been amended as indicated below.

1. (Twice Amended) A specimen cup for testing fluid specimen, when fluid specimen is contained therein, said cup comprising:

a container used to collect a the fluid specimen, ~~a container lid~~, said container having a top opening;

a cassette slidably received within a receptacle ~~hermetically sealed and custom~~ integrated with said container, said cassette further containing at least one chemical test strips means configured to provide an indication of a characteristic of ~~said~~ the specimen regarding a drug of abuse, when said at least one test strip is exposed to the drug of abuse; and

a lid configured to cover said top opening with the cassette inside, wherein said receptacle extends vertically below said lid.

2. (Amended) A specimen cup as in Claim 1, wherein ~~said~~ a bottom floor of said ~~cup~~ container is sloping from the backside downwardly at 1-3° towards the front side, said floor being configured to allowing said specimen to be channeled towards testing device said cassette.

3. (Amended) A specimen cup as in Claim 1, wherein said ~~cup~~ container has a ~~retracted~~ recessed flat face ~~designed~~ configured to move ~~the~~ a viewing area closer to said cassette.

4. (Twice Amended) A specimen cup as in Claim 1, wherein said cassette is ~~integrated~~ inserted into said receptacle of ~~with~~ said container through inserting said cassette into custom channels on said container to anchor said cassette's outside edges and orient said cassette for proper testing and viewing.

5. (Twice Amended) A specimen cup as in Claim 1, wherein the at least one test strip ~~said cassette~~ comprises test strips used to test for THC, COC, MAP, PCP and MOR.

6. (Twice Amended) A specimen cup as in Claim 1, wherein said cassette comprises a plurality of isolated test channels which house said at least one test strip for testing the drugs of abuse.

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7. (Amended) A specimen cup as in Claim 6, wherein each of said isolated test channels has a clear, sealed window hermetically sealed to a face of said cassette for viewing the results of ~~the~~ a test.

8. (Amended) A specimen cup as in Claim 7, wherein said clear, sealed window is formed by a transport fluid-resistant sheet laying on top of said test strips to prevent fluid specimen from accidentally spilling and ~~contaminate~~ contaminating the said at least one strips.

9. (Twice Amended) A specimen cup as in Claim 1, further comprising a hinged flap adjacent to a rim of said container, the hinged portion of the flap being affixed to an interior surface of said container in a position which partially blocks the opening of said container, said flap being configured to reduce, ~~to which once fluid specimen entered into said cup, said flap will prevent~~ the splashing of said fluid specimen ~~from splashing~~ during collection, testing, transport and storage.

10. (Twice Amended) A specimen cup as in Claim 1, further comprising a floating member configured to substantially fill a volume directly above said fluid specimen once said fluid specimen is entered into said cup, said floating member being configured to reduce the splashing of ~~prevent~~ said fluid specimen ~~from splashing~~ during collection, testing, transport and storage.

11. (Amended) A specimen cup as in Claim 1, wherein said cup is constructed ~~construed~~ of a material selected from the group ~~comprising~~ consisting of thermoplastics, specialty plastics, thermosets, and engineering plastics.

12. (Amended) A specimen cup as in Claim 11 ~~10~~, wherein said thermoplastics is selected from the group ~~comprising~~ consisting of polyamideimide (PAI), polyethersulfone (PES), polyarylsulfone (PAS), polyetherimide (PEI), polyarylate (PAR), polysulfone (PSO), polyamide (PA), polycarbonate (PC), styrene-maleic anhydride (SMA), chlorinated PVC (CPVC), poly(methylmethacrylate) (PMMA), styrene-acrylonitrile (SAN), polystyrene (PS), acrylonitrile-butadiene-styrene (PS), acrylonitrile-butadiene-styrene (ABS), poly(ethyleneterephthalate) (PET), poly(vinylchloride) (PVC), polyetherketone (PEK), polyetheretherketone (PEEK), polytetrafluoroethylene (PTFE), poly(phenylene sulfide) (PPS), liquid crystal polymer (CCP), nylon-6,6, nylon-6, nylon-6,12 nylon-11, nylon 12, acetal resin,



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low and high density propylene (PP), high density polyethylene (HDPE), low density polyethylene (LDPE), polystyrene, ethylene-vinyl acetate, poly-vinyl-acetate and polyacrylic.

13. (Amended) A specimen cup as in Claim 11 ~~40~~, wherein said cup is constructed from specialty plastics ~~is selected from the group comprising~~ consisting of fluorocarbon polymers and infusible film products, and Upilex polyimide film.

14. (Amended) A specimen cup as in Claim 11 ~~40~~, wherein said cup is constructed from thermosets ~~is selected from the group comprising~~ consisting of phenolics, epoxies, urea-formaldehyde and silicones.

15. (Amended) A specimen cup as in Claim 11 ~~40~~, wherein said cup is constructed from engineering plastics ~~is selected from the group comprising~~ consisting of acetyl resins, polyamide, polyetherimides, polyesters, liquid crystal polymers, polycarbonate resins, poly(phenylene ether) alloys, polysulfone resins and polyamideimide resins.

16. (Twice Amended) A specimen cup as in Claim 1, further comprising a dam structure attached to said cassette in order to form a recessed pooling area in said cassette wherein said cassette is configured to draw said testing fluid specimen from said cassette's end portion through said pooling area, ~~the said~~ pooling area being configured to expose said at least one cassette's interior test strips in the interior of said cassette to the fluid specimen, while ~~recessed~~ recessing the exposed portion of said at least one test strips sufficiently to minimize potential contamination of the test strips.

17. (Added) A specimen cup for testing fluid specimen contained therein, said cup comprising:

a container used to collect a fluid specimen;

a container lid; and

a cassette hermetically sealed and custom integrated with said container, said cassette further containing test strips to provide an indication of a characteristic of said specimen regarding a drug of abuse,

wherein a bottom floor of said container is sloping from the backside downwardly at 1-3° towards the front side allowing specimen to be channeled towards said cassette.

18. (Added) A specimen cup for testing fluid specimen contained therein, said cup comprising:

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a container used to collect a fluid specimen;

a container lid; and

a cassette hermetically sealed and custom integrated with said container, said cassette further containing test strips to provide an indication of a characteristic of said specimen regarding a drug of abuse,

wherein said container has a recessed flat face configured to move a viewing area closer to said cassette.

19. (Added) A specimen cup for testing fluid specimen contained therein, said cup comprising:

a container used to collect a fluid specimen;

a container lid;

a cassette hermetically sealed and custom integrated with said container, said cassette further containing test strips to provide an indication of a characteristic of said specimen regarding drug of abuse; and

a dam structure attached to said cassette in order to form a recessed pooling area in said cassette wherein said cassette is configured to draw said testing fluid specimen from said cassette's end portion through said pooling area, the pooling area being configured to expose said cassette's interior test strips to the fluid specimen, while being configured to recess the exposed portion of said test strips sufficiently to minimize potential contamination of the test strips.

20. (Added) A specimen cup for testing fluid specimen contained therein, said cup comprising:

a container used to collect a fluid specimen;

a container lid;

a cassette hermetically sealed and custom integrated with said container, said cassette further containing test strips to provide an indication of a characteristic of said specimen regarding drug of abuse; and

a hinged flap adjacent to a rim of said container, the hinged portion of the flap being affixed to an interior surface of said container in a position which partially blocks the opening of said container, said flap being configured to reduce, once fluid specimen



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entered into said cup, the splashing of said fluid specimen during collection, testing, transport and storage.

21. (Added) A specimen cup for testing fluid specimen contained therein, said cup comprising:

a container used to collect a fluid specimen;

a container lid;

a cassette hermetically sealed and custom integrated with said container, said cassette further containing test strips to provide an indication of a characteristic of said specimen regarding a drug of abuse; and

a floating member configured to substantially fill a volume directly above said fluid specimen, once said fluid specimen is entered into said cup, said floating member being configured to reduce the splashing of said fluid specimen during collection, testing, transport and storage.

22. (Added) A specimen cup as in Claim 1, wherein said lid is threaded to mesh with threads on a rim of said container, the meshing of said lid threads with the rim threads providing a substantially sealed closure.

23. (Added) A specimen cup as in Claim 1, wherein said lid is independent of said container.

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